AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

AMERICAN COLLEGE of CARDIOLOGY

March 4, 2009

To: Sarah McClain
From: Karen Lui
Re: Cardiac Rehabilitation

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) and the American College of Cardiology (ACC) appreciate having had the opportunity to meet with representatives of CMS and to submit these follow-up comments on the implementation of Section 144 of MIPPA (P.L. 110-275) in relation to the current cardiac rehabilitation NCD. As we discussed at our recent meeting, we are focusing our primary comments on changes to the current NCD that we believe the statute necessitates, and secondarily, recommendations that would clarify existing provisions in the NCD.

Physician Involvement/Role

Overview: We believe that one physician must accept responsibility for the overall functioning of the cardiac rehabilitation program whenever the program is providing care to Medicare beneficiaries. That physician may differ from day to day, as it is common for hospitals to assign such responsibility to a group of cardiologists rather than a single physician.

While the referring physician may choose to craft the plan of care, this role must not be confused with the physician who is statutorily "involved substantially in directing the progress of individual in the program." This statutory role, we believe, is part of the responsibility of the medical director of the program. Therefore, it is important for CMS to delineate whenever possible the general supervisory and management responsibilities of the medical director as well as what component services are legitimate billable physician services that contribute to the diagnosis and/or treatment of a specific patient.

Physician Standards: The physician responsible for directing Cardiac Rehabilitation, the Medical Director, should be a licensed board-certified/board eligible cardiologist or a physician with demonstrated expertise in the diagnosis and treatment of cardiovascular disease as well as expertise in exercise physiology, preventive cardiology and in the management of cardiac rehabilitation programs.

Specific Responsibilities of the Medical Director include:

1. Design and coordinate policies and procedures. This includes program development, ongoing quality improvement, clinical operations, and processes to facilitate patient referrals into cardiac rehabilitation.
2. Design and monitor patient intake evaluations.

3. Design and monitor clinical goal achievement on an individual and aggregate basis.
4. Coordinate program safety parameters and emergency management. This includes exclusion of inappropriate risk patients and protocols for emergency management.
5. Coordinate communication and interface with referring physicians.
6. Coordinate regulatory issues and compliance with reimbursement regulations.
7. Provide substantial involvement in the directing the progress of individuals in the program.

As noted above, the referring physician may choose to assume an expanded role for his/her own patients by setting goals for cardiac rehab participation, monitoring the patient's progress, discussing the cardiac rehab outcomes with the patient, and planning for the post cardiac rehabilitation maintenance phase. This does not preclude or usurp the role of the physician serving as medical director in terms of that physician fulfilling his/her responsibilities.

Selected References

1. King ML, Williams MA, Fletcher GF et al. Medical director responsibilities for outpatient cardiac rehabilitation/secondary prevention programs. A Scientific Statement from the American Heart Association/ American Association for Cardiovascular and Pulmonary Rehabilitation. *Circulation*. 2005;112:3354-3360

2. Ades PA. The role of the physician-medical director in cardiac rehabilitation. In: Cardiac Rehabilitation, 2007, Humana Press, Totowa, New Jersey, Kraus WE and Keteyian SJ Eds. Pages 263-269.

Assessment and Outcomes

Public Law 110—275 describes cardiac rehabilitation as an individualized treatment that includes physician-prescribed exercise; cardiac risk factor modification, psychosocial assessment, outcomes assessment and other items deemed necessary by the Secretary that are reasonable and necessary for the diagnosis or treatment of the patient's condition.

The CMS NCD 20:10 (March 22, 2006) defines cardiac rehabilitation services as including "a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling." Notably missing from the NCD definition, but present in the Public Law 110-275, are the components of **psychosocial assessment and outcomes assessment**.

The AACVPR and ACC leadership strongly support the expectation that cardiac rehabilitation services should include the assessment of clinical outcomes. To this point:

- There is growing evidence that the assessment of various behavioral and clinical outcomes helps to document and may also stimulate the quality of care being provided by cardiac rehabilitation programs.

- The collection of outcome data is included as one of several key performance measures for cardiac rehabilitation referral and delivery that were jointly developed and published by AACVPR, ACC, and the American Heart Association (AHA) in 2007 (see attached copy of the publication, which includes a sample version of an assessment tool).
- Outcomes assessment is a key "core component" of cardiac rehabilitation services, as defined in a previously published document from the AACVPR and AHA (see attached copy of the document).
- The assessment of psychosocial and clinical outcomes is a requirement for AACVPR cardiac rehabilitation program certification.

To help clarify the importance of outcomes assessment, AACVPR/ACC leadership recommends that the NCD be amended as follows:

Cardiac rehabilitation services include the assessment of clinical measures that help to document a patient's response to cardiac rehabilitation treatments. These measures typically include the following:

A. Cardiovascular risk factor control (e.g., blood pressure, blood lipids, blood glucose, weight, tobacco use, dietary habits, physical activity habits);

B. Co-morbid conditions that impact upon cardiac rehabilitation and/or cardiovascular risk (e.g., musculoskeletal limitations, sleep disorders, psychological disorders, etc.);

C. Patient adherence to prescribed medical and lifestyle therapies;

D. Recurrent cardiovascular symptoms and/or clinical events (re-hospitalization, myocardial infarction, death, etc.) tracked during the course of the patient's cardiac rehabilitation program;

E. Other outcomes, such as patient and/or staff satisfaction.

(Of note, the assessment of patient outcomes is an expectation for cardiac rehabilitation programs which are meeting standards of high quality care, whether designated as cardiac rehabilitation programs or as "intensive" cardiac rehabilitation programs.)

Because of its importance, and because of the amount of time and resources needed to for its completion, it would be appropriate to have a mechanism to bill for the assessment of outcomes in patients enrolled in a cardiac rehabilitation program.

Recommendation: We strongly encourage CMS to create a unique HCPCS code to address the statutory mandate for outcomes assessment. This code should reflect appropriate staff time as well as physician work.

Selected References

1. Thomas RJ, King M, Lui K, Oldridge N, Piña IL, Spertus J. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services. *Circulation*. 2007 Oct 2;116(14):1611-42.

2. Balady GJ, Williams MA, Ades PA, Bittner V, Comoss P, Foody JA, Franklin B, Sanderson B, Southard D. Core components of cardiac rehabilitation/secondary prevention programs: 2007 update: a scientific statement from the American Heart Association Exercise, Cardiac Rehabilitation, and Prevention Committee, the Council on Clinical Cardiology; the Councils on Cardiovascular Nursing, Epidemiology and Prevention, and Nutrition, Physical Activity, and Metabolism; and the American Association of Cardiovascular and Pulmonary Rehabilitation. *Circulation*. 2007 May 22;115(20):2675-82. Epub 2007 May 18.

3. Sanderson BK, Southard D, Oldridge N. AACVPR consensus statement. Outcomes evaluation in cardiac rehabilitation/secondary prevention programs: improving patient care and program effectiveness. *J Cardiopulm Rehab* 2004;24:68-79.

Appropriate Use of Cardiac Rehabilitation

Utilization of CPT code 93797

Effective March 22, 2006, CMS NCD 20:10 stated that **"**cardiac rehabilitation programs must be **comprehensive** and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling." Following 20:10, Public Law 110—275 describes cardiac rehabilitation as "**individualized treatment**" and that, "… an individualized treatment plan must include cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely related to the individual's care and treatment and is tailored to the individual's needs)." To that end, AACVPR and ACC believe that the current NCD for cardiac rehabilitation does not sufficiently provide guidance to operationalize the provision of both **comprehensive** and **individualized** treatment for cardiac patients. Notwithstanding CMS Transmittal 1417/CR 5912 (January 18, 2008), there continue to be numerous instances of MAC contradictions and instructions for utilization of CPT/HCPCS 93797.

Therefore, AACVPR/ACC recommends the following additional NCD language to further clarify the use of code 93797:

1. The revised NCD should state that code 93797 does not necessarily need to be used as an "exercise" code and may be used for either non-ECG-monitored exercise or for educational/counseling components of CR as both uses are appropriate and meet the descriptor for CPT 93797.

2. Hospitals and physician offices may use Code 93797 to provide for multiple cardiac rehabilitation services that modify cardiac risk factors, including education, counseling, and behavioral intervention.

3. Hospitals and physician offices may use Code 93797 on the same date of service as provision of Code 93798.

4. Hospitals and physician offices may use Code 93797 on more than one occasion per day as long as a patient receives anticipated benefit and each session lasts a minimum of 60 minutes.

5. It is not necessary that a patient receive an ECG-monitored cardiac rehabilitation session (93798) on the same day that a non-ECG monitored session (93797) is delivered (per CMS Transmittal 1417).

Selected References

1. Suaya JA, Shepard DS, Normand ST, Ades PA, Prottas J, Stason WB. Use of Cardiac Rehabilitation by Medicare Beneficiaries after Myocardial Infarction or Coronary Bypass Surgery. *Circulation*. 2007; 116:1653-1662.

2. CPT code 93797 is currently defined in the American Medical Association Physicians Current Procedural Terminology as "Physician services for outpatient cardiac rehabilitation; without continuous electrocardiographic [ECG] monitoring".

Cardiac Rehabilitation Program Delivery Models

There is a significant amount of evidence that the standard cardiac rehabilitation program consisting of 3 medically supervised sessions per week for 12 weeks is efficacious and results in good patient outcomes. However, there is growing evidence in the peer reviewed literature that cardiac rehabilitation programs using alternative delivery models of longer duration, but not involving a greater number of total sessions, demonstrate improved outcomes beyond the generally accepted standard delivery model. Hamm and colleagues[1] used an alternative program model with 623 cardiac patients that included a combination of medically supervised and home exercise training sessions for 12 months. Results demonstrated that peak oxygen uptake (VO_2) as measured by metabolic exercise testing continued to improve in 80% of the patients after 12 weeks in the program. The greatest improvement in peak VO_2 and peak role physical scores from the MOS SF-36 quality of life questionnaire were measured at 9 months (using 29-38 medically supervised exercise sessions).

In another similar study, Carlson et al used a combination of medically supervised exercise and home exercise for 25 weeks with 80 cardiac patients.[2] In the group of patients using a modified program format that weaned patients from medically supervised exercise to home exercise over a total of 36 sessions, results showed that, over the 25 weeks, patients in this group had statistically significant better outcomes compared to patients in the traditional format program: 25-week participation 92% vs. 76%; home exercise sessions per week 3.2 vs. 2.7; 23% greater total exercise frequency.

Additionally, the modified program was 50% less expensive and required 30% fewer staff compared to the traditional program.
Cardiac rehabilitation programs using alternative models of longer duration, but not involving a greater number of total sessions, allow the multidisciplinary health care professionals working in these programs to maintain regular contact with patients for a longer period of time. Merz and Rozanski have noted that it may require a minimum of one year to induce beneficial changes in risk factor modifications.[3] In this era of comprehensive cardiac rehabilitation services and secondary prevention, this may be extremely important to outcomes as many patients are asked to make multiple heart-healthy lifestyle changes and modify multiple risk factors for coronary heart disease.

Based on the research cited above, AACVPR and ACC recommend that the NCD allow cardiac rehabilitation programs to determine the most effective delivery model within reasonable limits. Currently some MACs narrowly and exclusively define cardiac rehabilitation as 3 medically supervised sessions per week and some require a minimum of two sessions weekly (see Cardiac Rehabilitation LCDs for Trailblazer and NGS). AACVPR and ACC recommend that the NCD allow for up to a maximum of 36 medically supervised sessions delivered over a maximum of 36 weeks. This provides programs the flexibility to determine the frequency and duration of medically supervised sessions that would be most beneficial to each individual patient.

Selected References

1. Hamm LF, Kavanagh T, Campbell RB, et al. Timeline for peak improvements during 52 weeks of outpatient cardiac rehabilitation. *J Cardiopulm Rehab* 2004;24:374-382.
2. Carlson JJ, Johnson JA, Franklin BA, et al. Program participation, exercise adherence, cardiovascular outcomes, and program costs of traditional versus modified cardiac rehabilitation. *Am J Cardiol* 2000;86:17-23.
3. Merz CN, Rozanski A. Remodeling cardiac rehabilitation into secondary prevention programs. *Am Heart J* 1996;132:418-427.

Defining Stable Angina

The scientific literature has previously definitively supported the benefits of cardiac rehabilitation services for patients with chronic stable angina. However, AACVPR and ACC believe that **multiple** MAC definitions for "Stable Angina" have created increasing barriers for patient utilization of cardiac rehabilitation services.

To that end, we recommend a revised NCD that specifically defines stable angina as:

(1) The presence of chest discomfort that is brought on by exertion and/or stress, that is relieved with rest or nitroglycerin, AND objective evidence for the presence of coronary heart disease by patient history (previous myocardial infarction, percutaneous coronary intervention, or coronary artery bypass surgery) or by testing (i.e., coronary artery stenosis by coronary angiography, a fixed or reversible defect on a nuclear stress test or a

stress echocardiogram, or evidence of previous infarction or current ischemia on an exercise stress ECG test).

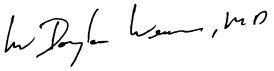
(2) The presence of anginal equivalent symptoms (e.g., dyspnea on exertion or upper abdominal distress) that is brought on by exertion and/or stress, that is relieved with rest or nitroglycerin, AND objective evidence for the presence of myocardial ischemia by testing (i.e., ischemia noted on a nuclear stress test, a stress echocardiogram, or an exercise stress ECG test). The presence of imaging-based ischemia may be defined on or off anti-ischemic medication regimens.

(3) This definition includes persons who meet these criteria prior to, OR after appropriate medical therapy.

Selected Reference:

Zipes DP, Libby P, Bonow RO, Braunwald E, eds. Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 7th ed. St. Louis, Mo; WB Saunders; 2005: 1281-1308.

Respectfully submitted,



W. Douglas Weaver, M.D., F.A.C.C.

Murray Low, EdD
President
American Association of Cardiovascular and Pulmonary Rehabilitation